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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/722,574

11/28/2003

Allan Tanghoj

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4958

136 7590 04/09/2007  
JACOBSON HOLMAN PLLC  
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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/09/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

58

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/722,574	TANGHOJ ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Andrew M. Gilbert	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 2-5 and 7-11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,6 and 12-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 6/23/2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. _____  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/17/06, 10/16/06</u> .  | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Acknowledgements***

1. This office action is in response to the reply filed on 1/16/2007.
2. In the reply, the applicant amended claims 1 and 19 and submitted replacement drawing sheet for Fig 12 and amended the specification to obviate the previous objection to the drawings.
3. Thus, claims 1, 6, 12-20 are pending, with claims 1 and 19 being independent.

### ***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on 10/16/2006 and 11/17/2006 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

### ***Claim Objections***

5. Claim 14 is objected to because of the following informalities: Claim 14 recites the limitation "said tubular member". There is a lack of antecedent basis for this claim limitation. The Examiner believes the limitation should read "said tubular protective member". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the

Art Unit: 3767

applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 6, 12-13, 18-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Kaye et al (6634498).

8. In reference to claims 1 and 19, Kaye et al discloses a kit for preparing a catheter for draining a human bladder, the kit comprising at least a first proximal catheter section (5) and a second distal catheter section (2); said two catheter sections defining a longitudinally extending passage therein, the sections being fixedly connected by a joint (1) and arranged in a coextending fashion with a tubular protective member (17 or 32) surrounding said first catheter section, said second distal catheter section being uncovered when said tubular protective member surrounds said first catheter section in said storage configuration, the kit further comprising a joint defining a substantially liquid tight seal (20 or 31) at a distal end of a substantially annular and longitudinally extending cavity provided between the proximal end portion of the first catheter section and an inner wall of the tubular protective member (18, Fig 4; Fig 8), the tubular protective member being removably connected to the second catheter section (17 or 32), so that, when the tubular protective member is removed, a proximal end portion of the first catheter section is exposed and ready for insertion into the human urethra (see discussion of Figs 4-5 and also Fig 7-8).

9. In reference to claim 6, Kaye et al discloses wherein a distal end of the second catheter section is provided with a removable liquid-tight seal (21, Fig 4).

Art Unit: 3767

10. In reference to claim 12 and 20, Kaye et al additionally discloses wherein the catheter has a hydrophilic surface and a liquid swelling medium is provided in the annular cavity (col 5, lns 44-61; col 6, lns 21-40).

11. In reference to claim 13, Kaye et al additionally discloses wherein the tubular protective member is detachably attached to an outer surface of the catheter when the tubular protective member is covering the first catheter section (17, 20, 1 in Fig 4; 21, 1, Fig 8).

12. In reference to claim 18, Kaye et al additionally discloses wherein the tubular protective member fastens to said second catheter section when the tubular protective member is covering the first catheter section (19, 20, 17, Fig 4; 32, 31, 33, Fig 8; and discussion of Figures 4 and 7-8 in col 5 and 6).

13. Claims 1, 13, 16-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Segawa (5863287).

14. In reference to claims 1 and 19, Segawa discloses a kit for preparing a catheter for draining a human bladder, the kit comprising at least a first proximal catheter section (2a) and a second distal catheter section (2b); said two catheter sections defining a longitudinally extending passage therein, the sections being fixedly connected by a joint (4) and arranged in a coextending fashion with a tubular protective member (11; Fig 4, 7) surrounding said first catheter section, said second distal catheter section being uncovered when said tubular protective member surrounds said first catheter section in said storage configuration, the kit further comprising a joint defining a substantially liquid

Art Unit: 3767

tight seal (18, Fig 4, 7) at a distal end of a substantially annular and longitudinally extending cavity provided between the proximal end portion of the first catheter section and an inner wall of the tubular protective member (Fig 4; col 5, lns 33-40, col 6, lns 22-34), the tubular protective member being removably connected to the second catheter section (Fig 1, 4), so that, when the tubular protective member is removed, a proximal end portion of the first catheter section is exposed and ready for insertion into the human urethra (Fig 1, 4, wherein the Examiner notes that Segawa is fully capable of insertion and that the Applicant has not structurally defined what constitutes a urinary catheter).

15. In reference to claim 13, Segawa additionally discloses wherein the tubular protective member is detachably attached to an outer surface of the catheter when the tubular protective member is covering the first catheter section (Fig 4).

16. In reference to claim 16, Segawa additionally discloses further comprising a ribbed portion (4, Fig 4-7) between said first and second sections.

17. In reference to claim 17, Segawa additionally discloses wherein said tubular protective member fastens to said second catheter section through engagement with said ribbed portion (13, 16, 18, Fig 4-7).

18. In reference to claim 18, Segawa additionally discloses wherein the tubular protective member fastens to said second catheter section when the tubular protective member is covering the first catheter section (Fig 4, 7).

### ***Double Patenting***

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

Art Unit: 3767

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

20. Claims 1, 6, 12-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-26, 54-65 of copending Application No. 10/184081 or claims 1-21 of copending Application No. 10/537014. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application are merely broader than the copending parent case. Thus, the invention claimed in the current application is merely generic to the species claimed in the parent application and it has been held that the generic invention is anticipated by the species.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Arguments***

21. Applicant's arguments with respect to claims 1, 6, 12-20 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

22. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Reif et al (4811847); Powers (3854483).

23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.



Art Unit: 3767

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER.

